



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/613,117

07/03/2003

John P. Sopp

LIFE-090CON4

4207

24353

7590

12/17/2004

BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER

STAFIRA, MICHAEL PATRICK

ART UNIT

PAPER NUMBER

2877

DATE MAILED: 12/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/613,117

Applicant(s)

SOPP ET AL

Examiner

Michael P. Stafira

Art Unit

2877

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/3/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. In the specification, please amend so that all cross-referenced applications are listed and not left blank.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 38, "a second pressure surface" is not defined in the specification and is unclear as to which structural element it represents. Claims 39-42 depend on the limitations of claim 38 and therefore hold the same differences.

In as much as the claim(s) can be understood in light of the 112 rejection(s) made above, the following rejection(s) apply:

Claim Rejections - 35 USC § 103

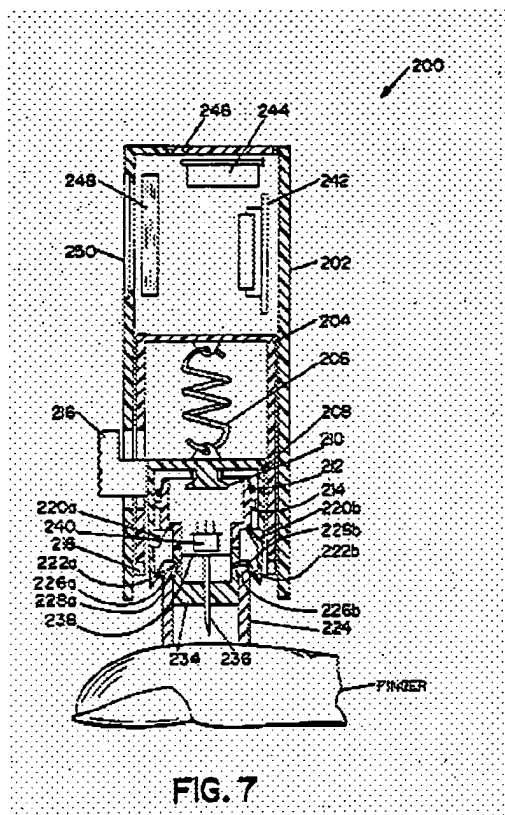
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

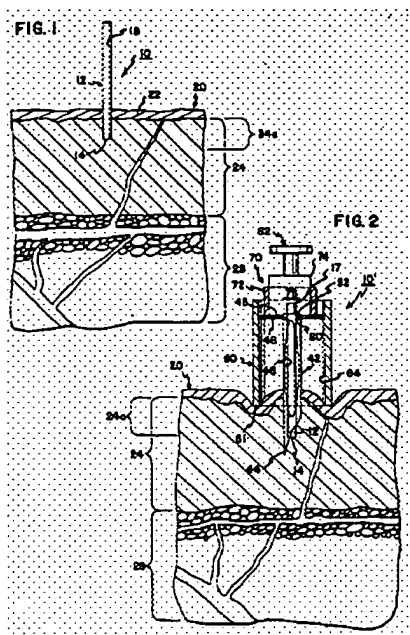
4. Claims 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia et al. ('403) in view of Erickson et al. ('184).

Claim 38

Garcia et al. ('403) discloses providing a sampling device (Fig. 7, Ref. 200) comprising a sampling needle (Fig. 7, Ref. 236) having an axis and a distal end (See Fig. 7), a first pressure surface (Fig. 7, Ref. 224) at least partially surrounding said needle in spaced relation thereto (See Fig. 7), wherein said needle (Fig. 7, Ref. 236) and said first pressure surface (Fig. 7, Ref. 224) are movable relative to one another along a path of travel generally parallel to said axis with said needle (See Fig. 7), and a second pressure surface (Fig. 7, Ref. 214) at least partially surrounding said needle and movable therewith (See Fig. 7), said second pressure surface (Fig. 7, Ref. 214) axially spaced from said distal end of said needle by a distance approximating a desired penetration of said needle into said skin (Col. 10, lines 36-45); and biasing said first pressure surface (Fig. 7, Ref. 224) to a position wherein said distal end of said needle (Fig. 7, Ref. 236) is recessed behind said first pressure surface (See Fig. 7).



Garcia et al. ('403) substantially teaches the claimed invention except that it does not teach urging the first pressure surface against the skin with a force sufficient to define a pressurized zone of interstitial fluid opposing the needle. Erickson et al. ('184) shows that it is known to teach urging a first pressure surface (Fig. 2, Ref. 64) against the skin (Fig. 2, Ref. 20) with a force sufficient to define a pressurized zone of interstitial fluid opposing said needle (Fig. 2, Ref. 42)(Col. 7, lines 31-39) for a fluid sampling device. It would have been obvious to combine the device of Garcia et al. ('403) with the creating a pressurized zone of fluid of Erickson et al. ('184) for the purpose of providing substantial fluid flow, therefore increasing the amount of fluid reaching the sample to provide a accurate measurement.

**Claim 39**

Garcia et al. ('403) in view of Erickson et al. ('184) discloses the claimed invention except for the needle penetrates the skin until the second pressure surface is caused to contact the skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Garcia et al. ('403) in view of Erickson et al. ('184) with second pressure surface is in contact with the skin since it was well known in the art that depending on the location of the sampling that the second pressure surface is going to contact the skin in the sampling is in a fatty part of tissue. Therefore, increasing the probability of retrieving a sample from the sample area.

Claim 40

Garcia et al. ('403) in view of Erickson et al. ('184) discloses the claimed invention except for the second pressure surface to a position wherein said first pressure surface is recessed behind said second pressure surface. It would have been obvious to one having ordinary skill in

Art Unit: 2877

the art at the time the invention was made to combine Garcia et al. ('403) in view of Erickson et al. ('184) with first pressure surface is recessed behind the second pressure surface since it was well known in the art that depending on the distance given for the stop (214) the probe (234) can be projected past tube (224), therefore increasing the contact surface area on the surface of the sample making it more stable.

Claim 41

Garcia et al. ('403) in view of Erickson et al. ('184) discloses the claimed invention except for the first pressure surface is initially biased with about three to about four pounds per inch and said second pressure surface is initially biased with about one to about two pounds per inch. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine three to four pounds per inch with Garcia et al. ('403) in view of Erickson et al. ('184) since it was well known in the art that having enough pressure to insert the needle into the skin will produce ample amount of fluid for measurement, therefore increasing reliability.

Claim 42

Garcia et al. ('403) further discloses collecting body fluid within the skin and transporting it through the needle to a testing area (Col. 10, lines 45-49).

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


Art Unit: 2877

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Stafira whose telephone number is 571-272-2430. The examiner can normally be reached on 4/10 Schedule Mon.-Thurs..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory Toatley can be reached on 571-272-2800 ext. 77. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael P. Stafira
Primary Examiner
Art Unit 2877

Application/Control Number: 10/613,117

Page 8

Art Unit: 2877

December 13, 2004